December 6, 2019

Rebound Therapeutics
Naomi Gong
VP of Regulatory Affairs
13900 Alton Parkway Suite 120
Irvine, California 92618

Re: K191861
Trade/Device Name: Aurora Surgiscope System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: November 12, 2019
Received: November 13, 2019

Dear Naomi Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191861

Device Name
AURORA Surgiscope System

Indications for Use *(Describe)*

The Aurora Surgiscope System is intended for use in endoscopic neurosurgery and pure neuroendoscopy (i.e. ventriculoscopy) for visualization, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of cysts, tumors and other obstructions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

SUBMITTER

Rebound Therapeutics Corporation
13900 Alton Parkway, STE 120
Irvine, CA 92618

Contact Person: Naomi Gong, RAC
Vice President of Regulatory Affairs
Telephone: (949) 305-8111
Email: ngong@reboundtx.com
Date Prepared: July 10, 2019

DEVICE

Name of Device: AURORA Surgiscope System
Regulation Number: 882.1480, 882.4800
Regulation Name: Neurological endoscope, Self-retaining retractor for neurosurgery
Regulatory Class: II
Product Code: GWG, GZT

PREDICATE DEVICE

AURORA Surgiscope System, K182211

DEVICE DESCRIPTION

The Aurora Surgiscope System consists of two components: (1) a sterile, single use, neurological endoscope and (2) a non-sterile, reusable control unit, Image Control Box (ICB).

The Aurora Surgiscope includes the following components:

- Sheath
- Camera
- LED (Light Emitting Diodes)
- Sheath Cable
- Obturator

The Sheath is fabricated from ABS plastic and is cylindrically shaped. It acts as both the insertion portion and instrument channel of the endoscope. Depth markers are located on both sides of the Sheath in 1 cm increments to aid with device insertion. LEDs are embedded into the interior wall of the Sheath that provide illumination of the surgical field. A larger diameter plastic ring, Camera mount (or Fixation ring), is located at the proximal end of the Sheath and may be used with fixation arm(s) to hold/fix the device.

The Camera assembly is rigidly attached to the Camera Mount and positioned to produce a forward view (0° direction) of the surgical site. An optical lens and prism are also incorporated for imaging.

The Surgiscope electronics are connected to the ICB by a flexible shielded Sheath Cable. The cable exits from the rear of the Camera housing and is connected to the ICB during system set-up.

The Obturator is pre-loaded into the Sheath. Its distal tip is fabricated from clear plastic and is conical shaped to minimize injury to tissue during insertion. At the proximal end, a plastic handle is used for

removal of the Obturator from the Sheath and has an attachment on the handle to secure stereotactic instruments for neuronavigation. A stainless steel tube connects the Obturator tip and handle.

The Image Control Box (ICB) controls the real-time video image that it receives from the camera on the Surgiscope. It also delivers the real-time video to an external Display Monitor and provides isolated power to the Surgiscope LEDs and camera. The ICB is supplied with two cables: an isolated 110V power cable to be connected to an AC electrical outlet and a cable which is to be connected to the Display Monitor in the operating room.

The user interface is a membrane keypad with buttons that can be depressed for image adjustment, such as zoom, contrast, brightness, and orientation. The connections to the Surgiscope, Display Monitor and Power are the side of the ICB as well as the ON/OFF switch.

INDICATIONS FOR USE

The Aurora Surgiscope System is intended for use in endoscopic neurosurgery and pure neuroendoscopy (i.e. ventriculoscopy) for visualization, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of cysts, tumors and other obstructions.

SUMMARY OF NON-CLINICAL TESTING

The following testing was conducted or adopted to demonstrate the safe and effective use and substantial equivalence to the predicates.

- Biocompatibility Testing per ISO 10993-1, including Cytotoxicity (MEM Elution), Sensitization (Kligman Maximization), Irritation (Intracutaneous Injection), Systemic Toxicity (Systemic Injection), Hemolysis (In direct), Materials Mediated Pyrogenicity were adopted
- Electrical Safety and Enclosure Protection per IEC 60601-1 and IEC 60529-1
- Emissions and Immunity per IEC 60601-1-2
- Particulate Testing per USP <788>
- Sterilization per ISO 11135-1 to validate a SAL of 10^{-6} was adopted
- Packaging and Shelf-life per ISTA 2A and ASTM F1980
- Design Verification testing
- Software and System Verification and Validation

COMPARISON TO PREDICATE

	PREDICATE Device	**SUBJECT Device**
	Aurora Surgiscope System (K182211)	**Aurora Surgiscope System**
INDICATIONS FOR USE	The Aurora Surgiscope System is intended for use in endoscopic neurosurgery and pure neuroendoscopy (i.e. ventriculoscopy) for visualization, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of cysts, tumors and other obstructions.	Same
Sheath (Trocar)	The device is a trocar: ▪ OD ≤ 11.5mm, ID = 8 mm ▪ Lengths = 70, 100, 130 mm ▪ Incremental depth markings ▪ Single working channel ▪ Mounting ring for camera ▪ With obturator (conical shape, rounded tip)	Same
Materials	Sheath: ABS PET Adhesives	Same

	PREDICATE Device Aurora Surgiscope System (K182211)	SUBJECT Device Aurora Surgiscope System
	Marker: White Ink Camera mount ring: ABS Obturator: Polycarbonate, 304 SS, ABS, adhesives	
Endoscope	The device incorporates an endoscope with optics (lens, prism): Direction of View = 0° Depth of field = 0 to 3 cm	Same
Light Source	6 LED lights incorporated into inner dia. of sheath near distal end	Same
Camera	Integrated CMOS camera and electronics on endoscope	Equivalent
Image Control Box (control unit)	▪ Electronics (Circuit boards, CPU with software control) ▪ Rotational potentiometers for image adjustment by user	▪ Equivalent ▪ Keypad buttons for image adjustment by user
Other (accessories)	Power supply and cable Display cable	Equivalent
Display Monitor	Not supplied	Same
Access to the surgical site	Sheath and Obturator used to access the surgical site. The Obturator extends 10mm beyond distal end of sheath	Same
Single working channel	Removal of obturator reveals working channel which provides visual access for camera and working access for instruments, including suction and irrigation.	Same
Image acquisition	Image acquisition is achieved through an integrated camera	Same
Image processing	Image is digitally processed by control unit	Same
Image display	External display monitor connection	Same
Illumination	Illumination is achieved via direct LED light sources incorporated into the device.	Same
Visualization	CMOS, color, video, camera (with software) incorporated at proximal end of the device and controlled via control unit.	Equivalent
Biocompatibility of Surgiscope	Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	Same
Use and how supplied	Surgiscope: single use, sterile ICB (control unit): reusable, non-sterile	Same
Sterilization Method of Surgiscope	Ethylene oxide gas	Same

CONCLUSION

The conclusion based upon the review of performance data provided in this submission and the comparison of indicated use, design, materials, principle of operation and overall technological characteristics, the Aurora Surgiscope System has been determined, by Rebound Therapeutics Corporation, to be substantially equivalent to the predicate device.